

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James E. GALEN

Conf. No.: **Unassigned**

DIVISIONAL

Appln. No.: **of 09/453,313**

Group Art Unit in Parent: **1636**

Filed: **January 5, 2004**

Examiner in Parent: **Guzo, D.**

For: **PLASMID MAINTENANCE SYSTEM FOR ANTIGEN DELIVERY**

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97 and 1.98**

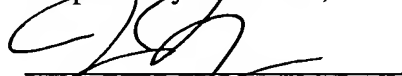
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form which are all the references of record in parent application No. 09/453,313. Applicant is not submitting duplicate copies of these references, but requests that they be listed on the face of any patent granted on the above application (see 37 C.F.R. §1.98(d)).

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



Drew Hissong
Registration No. 44,765

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: January 5, 2004

Substitute for Form 1449 A & B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	DIV of USSN 09/453,313
				Confirmation Number	0000
				Filing Date	January 5, 2004
				First Named Inventor	James E. GALEN
				Art Unit	1636
				Examiner Name	Guzo, D.
Sheet	1	of	4	Attorney Docket Number	A-8703

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US 4,735,801		04/05/1998	Stocker
		US 4,764,370		08/16/1988	Fields et al
		US 5,459,072		10/17/1995	McKay et al
		US 5,643,771		07/01/1997	Stocker
		US 5,672,345		09/30/1997	Curtiss III
		US 5,695,983		12/09/1997	Miller et al
		US 5,763,270		06/09/1998	Eastman et al
		US 5,770,214		06/23/1998	Dougan et al
		US 5,804,194		09/08/1998	Dougan et al
		US 5,851,519		12/22/1998	Dougan et al
		US 5,674,703		10/07/1997	Woo et al
		US 5,527,529		06/18/1996	Dougan et al
		US 4,760,022		07/26/1998	Molin et al
		US 5,853,718		12/29/1998	Molin et al
		US 5,922,583		07/13/1999	Morsey
		US 5,545,541		08/13/1996	Molin et al
		US 5,824,538		10/20/1998	Branstrom et al

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Summers, <i>The Biology of Plasmids</i> , pages 65-91 (1996)	
		Jensen et al, <i>Molecular Microbiology</i> , 17(2):205-210 (1995)	
		Pecota et al, <i>Applied and Environmental Microbiology</i> , 63(5):1917-1924 (1997)	
		Boe et al, <i>Journal of Bacteriology</i> , 169(10):4646-4650 (1987)	
		Gerdes et al, <i>Annu. Rev. Genet.</i> , 31:1-31 (1997)	
		Gulyaev et al, <i>J. Mol. Biol.</i> , 273:26-37 (1997)	
		Franch et al, <i>J. Mol. Biol.</i> , 273:38-51 (197)	
		Mikkelsen et al, <i>Molecular Microbiology</i> , 26(2):311-320 (1997)	
		Franch et al, <i>Mol. Microbiol.</i> , 21(5):1049-1060 (1996)	
		Gerdes et al, <i>J. Mol. Biol.</i> , 190:269-279 (1986)	
		Gerdes et al, <i>Genetic Eng.</i> , 19:49-61 (1997)	
		Gerdes et al, <i>J. of Bacteriology</i> , 161(1):292-298 (1985)	
		Wu et al, <i>Biotechnology and Bioeng.</i> , 44:912-921 (1994)	
		Wood et al, <i>Biotechnology and Bioeng.</i> , 38:397-412 (1991)	
		Gerdes, <i>Biotechnology</i> , 6:1402-1405 (1998)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

Substitute for Form 1449 A & B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	DIV of USSN 09/453,313
				Confirmation Number	0000
				Filing Date	January 5, 2004
				First Named Inventor	James E. GALEN
				Art Unit	1636
				Examiner Name	Guzo, D.
Sheet	2	of	4	Attorney Docket Number	A-8703

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Bravo et al, <i>Mol. Gen. Genet.</i> , 210:101-110 (1987)	
		Ruiz-Echevarria et al, <i>Mol. Microbiol.</i> , 5(11):2685-2963 (1997)	
		Ruiz-Echevarria et al, <i>Gen. Genet.</i> , 248:599-609 (1995)	
		Ruiz-Echevarria et al, <i>J. Mol. Biol.</i> , 247:568-571 (1995)	
		Bravo et al, <i>Mol. Gen. Genet.</i> , 215:146-151 (1988)	
		Nordstrom et al, "Control of Replication of Bacterial Plasmids: Molecular Biology, and Physiology of the Plasmid R1 System", Academic Press Inc., pages 71-91 (1984)	
		Gerdes et al, "Antisense RNA-Regulated Programmed Cell Death", Annual Rev. Inc, pages 1-31 (1997)	
		Nordstrom et al, BIOSCI, pages 294-300 (1994)	
		Pedersen et al, <i>Mol. Microbiol.</i> , 32(50):1090-1102 (1999)	
		Melton-Celsa et al, "The Structure, Biology, and Relative Toxicity for Cells and Animals of Shiga Toxin Family Members", Uniformed Services University of the Health Sciences, pages 1-23	
		Dolfing et al, <i>ASM News</i> , 62(3):117-119 (1996)	
		Keeler et al, <i>Handbook of Natural Toxins</i> , 8:313-327	
		Konowalchuck et al, <i>The Lancet</i> , 351:1003 (1998)	
		Endo et al, <i>Eur. J. Biochem.</i> , 171:45-50 (1988)	
		Gerdes et al, <i>Proc. Natl. Acad. Sci., USA</i> , 83:3116-3120 (1986)	
		Gyles, <i>Can. J. Microbiol.</i> , 38:732-746 (1992)	
		Jackson et al, <i>Federation of European Microbiological Societies</i> , 44:109-114 (1987)	
		Tesh et al, <i>Inf. and Immun.</i> , 61(8):3392-3402 (1993)	
		Lindgren et al, <i>Inf. and Immun.</i> , 62(2):623-631 (1994)	
		Sung et al, <i>J. of Bacteriol.</i> , 172(11):6386-6395 (1990)	
		Muhldorfer et al, <i>Inf. and Immunol.</i> , 64(2):495-502 (1996)	
		Schmitt et al, <i>Inf. and Immunol.</i> , 59(3):1065-1073 (1991)	
		Weinstein et al, <i>J. of Bacteriol.</i> , 170(9):4223-4230 (1988)	
		Gyles et al, <i>Microbial Pathogenesis</i> , 5:419-426 (1988)	
		Paton et al, <i>Infect. and Immunity</i> , 63(7):2450-2458 (1995)	
		Paton et al, <i>Microbial Pathogenesis</i> , 15:77-82 (1993)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

Substitute for Form 1449 A & B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	DIV of USSN 09/453,313
				Confirmation Number	0000
				Filing Date	January 5, 2004
				First Named Inventor	James E. GALEN
				Art Unit	1636
				Examiner Name	Guzo, D.
Sheet	3	of	4	Attorney Docket Number	A-8703

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Stein et al, <i>Nature</i> , 355:748-750 (1992)	
		Per-Georg et al, <i>Int. J. Biol. Macromol.</i> , 17(3-4):199-204 (1995)	
		Per-Georg et al, <i>Chemistry & Biology</i> , 3(4):263-275 (1996)	
		Ling et al, <i>Biochemistry</i> , 37:1777-1788 (1998)	
		Hovde et al, <i>Proc. Natl. Acad. Sci., USA</i> , 85:2568-2572 (1988)	
		Yamasaki et al, <i>Microbial Pathogenesis</i> , 11:1-9 (1991)	
		Jackson et al, <i>J. of Bacteriology</i> , 172(6):3346-3350 (1990)	
		Gordon et al, <i>Inf. and Immun.</i> , 60(2):485-490 (1992)	
		Bosworth et al, <i>Inf. and Immun.</i> , 64(1):55-60 (1996)	
		Jackson, <i>J. of Bacteriology</i> , 172(2):653-658 (1990)	
		Clark, <i>Mol. Microbiology</i> , 19(4):891-899 (1996)	
		Bast, <i>Inf. and Immun.</i> , 65(6):2019-2028 (1997)	
		Perera et al, <i>J. of Bacteriology</i> , 173(3):1151-1160 (1991)	
		Perera et al, <i>Inf. and Immun.</i> , 59(3):829-835 (1991)	
		Downes et al, <i>Inf. and Immun.</i> , 56(8):1926-1933 (1988)	
		Su et al, <i>Inf. and Immun.</i> , 60(8):3345-3359 (1992)	
		Su et al, <i>Microbial Pathogenesis</i> , 13:465-476 (1992)	
		Richardson et al, <i>Inf. and Imm.</i> , 60(10):4154-4167 (1992)	
		Nelson et al, "Biological Activity of Verocytotoxin (VT)2c and VT1/VT2c chimeras in the rabbit model", Elsevier Science, pages 245-249 (1994)	
		Bielaszewska et al, <i>Inf. and Immun.</i> , 65(7):2509-2516 (1997)	
		Streatfield et al, <i>Proc. Natl. Acad. Sci., USA</i> , 89:12140-12144 (1992)	
		Acheson et al, <i>Inf. and Immun.</i> , 64(1):355-357 (1996)	
		Wadolowski et al, <i>Inf. and Immun.</i> , 58(12):3959-3965 (1990)	
		Karpman et al, <i>J. of Infect. Dis.</i> , 175:611-620 (1997)	
		Louise et al, <i>J. of Infect. Dis.</i> , 172:1397-1401 (1995)	
		Boyd et al, <i>Nephron</i> , 51:207-210 (1989)	
		Zoja et al, <i>J. Lab. Clin. Med.</i> , 120(2):229-238 (1992)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

Substitute for Form 1449 A & B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	DIV of USSN 09/453,313
				Confirmation Number	0000
				Filing Date	January 5, 2004
				First Named Inventor	James E. GALEN
				Art Unit	1636
				Examiner Name	Guzo, D.
Sheet	4	of	4	Attorney Docket Number	A-8703

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		McDaniel et al, <i>Proc. Natl. Acad. Sci., USA</i> , 932:1664-1668 (1995)	
		Jarvis et al, <i>Proc. Natl. Acad. Sci., USA</i> , 92:7996-8000 (1995)	
		Jarvis et al, <i>Inf. and Immun.</i> , 64(11):4826-4829 (1996)	
		Sixma et al, <i>Biochemistry</i> , 32:191-198 (1993)	
		Mangeny et al, <i>Cancer Res.</i> , 53:5314-5319 (1993)	
		Frank et al, <i>J. of Clin. Microbiology</i> , 33(12):3174-3178 (1995)	
		Kim et al, <i>Micro. Immunol.</i> , 41(10):805-808 (1997)	
		Butterton et al, <i>Infect. and Immunity</i> , 65(6):2127-2135 (1997)	
		Nataro et al, <i>Amer. Soc. for Microbiology</i> , 11:164-178 (1998)	
		Taga et al, <i>Blood</i> , 90(7):2757-2767 (1997)	
		Haddad et al, <i>J. of Bacteriology</i> , 175(16):4970-4978 (1993)	
		Gannon et al, <i>J. of General Microbiology</i> , 136:1125-1135 (1990)	
		O'Brien et al, <i>Micro. and Immunol.</i> , 180:66-93 (1992)	
		Montfort et al, <i>J. of Biological Chem.</i> , 262(11):5398-5403 (1987)	
		Lindgren et al, <i>Inf. and Immun.</i> , 61(9):3832-3842 (1993)	
		Rasmussen et al, <i>Mol. Gen. Genet.</i> , 209(1):122-128 (1987)	
		Gerdes et al, <i>Mol. Microbiol.</i> , 4(11):1807-1818 (1990)	
		Ito et al, <i>Microbial Pathogenesis</i> , 8:47-60 (1990)	
		Fraser et al, <i>Structural Biology</i> , 1(1):59-64 (1994)	
		Yu et al, <i>Mol. Microbiol.</i> , 6(3):411-417 (1992)	
		Thisted et al, <i>J. Mol. Biol.</i> , 247:859-873 (1995)	
		Thisted et al, <i>The EMBO Journal</i> , 13(8):1950-1959 (1994)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.